

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Appellant(s): James D. Lewis, Jr., et al.
Appl. No.: 10/779,993
Conf. No.: 1329
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Title: ALBUMIN IN A FLEXIBLE POLYMERIC CONTAINER
Art Unit: 3728
Examiner: Jila M. Mohandesi
Docket No.: BTHT-5755 D1 US (112713-1354)

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Commissioner for Patents
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APPELLANTS' REPLY BRIEF

Sir:

I. INTRODUCTION

Appellants submit Appellants' Reply Brief in response to the Examiner's Answer dated January 8, 2008 pursuant to 37 C.F.R. § 41.41(a). Appellants respectfully submit the Examiner's Answer has failed to remedy the deficiencies with respect to the Final Office Action dated July 24, 2007 as noted in Appellants' Appeal Brief filed on October 11, 2007 for at least the reasons set forth below. Accordingly, Appellants respectfully request that the obviousness rejections of pending Claims 1-12, 22, 25-26 and 28-33 be reversed.

II. THE EXAMINER HAS STILL FAILED TO ESTABLISHED A *PRIMA FACIE* CASE OF OBVIOUSNESS WITH RESPECT TO CLAIMS 1-12, 22, 25-26 AND 28-33

Appellants respectfully request that the Board reverse the 35 U.S.C. §103 rejections because the Examiner has still failed to demonstrate that the cited references, alone or in combination, disclose or suggest every element of independent Claims 1 and 30. Independent Claim 1 recites, in part, a flexible container containing an albumin concentration of 20%. Independent Claim 1 also recites, in part, that the container also has a seal area free of the albumin concentration and a heat seal formed on the seal area to create a fluid-tight chamber for the albumin concentration. Independent Claim 30 recites, in part, an albumin concentration added through the opening so that the seal area is free of albumin concentration.

In alternative embodiments, Appellants have developed efficient, inexpensive and user friendly methods of packaging albumin to produce novel flexible, sealed containers comprising an albumin concentration. The claimed flexible containers made by these methods eliminate the drawbacks associated with packaging albumin in glass vials and using heat sealing processes to seal off albumin-containing packages. In contrast, Appellants respectfully submit that the cited references are deficient with respect to the claimed invention.

1. *Johnston* remains deficient with respect to Claims 1-7, 11-12, 22, 25 and 28-33

Johnston fails to disclose or suggest a flexible container containing an albumin concentration of 20% as required by Claim 1. In fact, *Johnston* fails to even disclose or suggest albumin in a container anywhere in his disclosure. *Johnston* also fails to disclose or suggest that the container has a seal area free of the albumin concentration and a heat seal formed on the seal area to create a fluid-tight chamber for the albumin concentration as required by Claim 1. Finally, *Johnston* fails to disclose or suggest an albumin concentration is added through the opening so that the seal area is free of albumin concentration as required by Claim 30.

The skilled artisan would also have no reason to arrive at the claimed invention in view of *Johnston* because they would have no reasonable expectation of success. *Johnston* is directed to a flexible film that can be run through a form-fill-seal packaging machine to create a flexible

container. The container is capable of storing drug solutions or plasma. See, *Johnston*, column 6, lines 50-66 and column 2, lines 40-45. Nevertheless, *Johnston* fails to teach or even recognize the problems or difficulties of packaging albumin in a sealed flexible container. Moreover, *Johnston* provides no processes or techniques to successfully fill his container with an albumin concentration and then seal the container while avoiding the problems of albumin degradation and albumin interference at the seal area. Accordingly, the skilled artisan would not be able to manufacture a sealed container having albumin in accordance with the present claim merely by using *Johnston* because of the inherent difficulties associated therewith and would have no reasonable expectation of success in view of *Johnston*.

The Examiner asserts that *Johnston* discloses a seal area where the fitment/fill tube is heat sealed to the outside layer of the flexible bag will be free of albumin concentration because this seal is formed prior to filling the flexible bag with albumin. Nevertheless, *Johnston* still has no disclosure whatsoever with respect to a container containing a 20% albumin concentration or an albumin concentration added through the opening of a flexible bag in accordance with the present claims.

The Examiner asserts that the flexible bag of *Johnston* is suitable for storing albumin because the flexible bag of *Johnston* is suitable and utilized in the medical industry for containing, inter alia, parenteral solutions, dialysis solutions, frozen drugs and plasma. The Examiner also asserts that it would have been obvious to substitute one known element for another known element because it would have yielded predictable results to the skilled artisan and would have been within the technical grasp of the skilled artisan at the time of the invention.

Appellants respectfully disagree with the Examiner's assertions and submit that the Examiner is mischaracterizing *Johnston* in an attempt to arrive at the claimed invention. Just because the bag disclosed in *Johnston* can store one biological product does not automatically mean that it would have been obvious or desirable for the skilled artisan to store a different biological product in that same bag. In particular, the ability to store plasma in a container does not automatically equate to storing albumin in that same container solely because plasma contains albumin. In addition to approximately 4% albumin, human plasma contains hundreds of other components including, for example, clotting factors VIII and IX, immunoglobulins, transport proteins such as haptoglobin and transferrin, and enzyme inhibitors. Consequently, plasma exhibits properties quite different from a 20% albumin solution as recited in the claims,

which result in very different packaging requirements. In particular, concentrated albumin solutions are highly susceptible to denaturation when exposed to heat, making such solutions difficult to sterilize and challenging to package in heat-sealable plastic containers such as that of *Johnston*. Although *Johnston* lists certain compounds that can be stored in his bag, *Johnston* fails to realize or appreciate the practical difficulties and problems associated with making a flexible, heat sealed container having a heat sensitive albumin protein solution in accordance with the present claims.

The Examiner further asserts that, when there is a design need or market pressure to solve a problem and there are a finite number of identifiable, predictable solutions, a person of ordinary skill in the art has good reasons to pursue the known options within his or her technical grasp. In response, Appellants respectfully submit that it is the Appellants who have realized the problem and the solution to overcome the problem. For example, Appellants discovered the novel and non-obvious processes of the present specification (see related U.S. Patent No. 6,718,735) that produce the present claimed flexible containers comprising albumin.

Moreover, as noted above, albumin can readily congeal or degrade and become useless after exposure to heat. As a result, the skilled artisan would ordinarily be led away from heat sealing any container containing albumin. In addition, because albumin operates as an insulator, the presence of a high albumin concentration on the seal area before heat sealing would be expected to result in a compromised or weakened heat seal, which makes it difficult to manufacture heat sealed containers containing albumin. See specification, page 2 lines 23-31. The present application discloses novel and non-obvious albumin containers that overcome these problems, for example, by using methods that ensure that the seal area is free of albumin when a heat seal is formed on the seal area. See specification, page 15 lines 4-10. Accordingly, the Examiner has failed to provide sufficient reasons why or how the skilled artisan would overcome these problems by using *Johnston*.

In sum, *Johnston* fails to disclose or suggest a number of elements of independent Claims 1 and 30. Moreover, the skilled artisan has no reason to arrive at a heat sealed container holding albumin in accordance with the present claims in view of *Johnston*. Accordingly, Appellants respectfully submit that *Johnston* fails to render obvious Claims 1 and 30, as well as Claims 2-7, 11-12, 22, 25, 28-29 and 31-33 that depend from Claims 1 and 30, and the obviousness rejection should be reversed.

2. *Johnston and Bacehowski* remain deficient with respect to Claims 8 and 26 that depend from Claim 1

As discussed above, *Johnston* fails to disclose or suggest every element of independent Claim 1. *Bacehowski* fails to remedy the deficiencies of *Johnston*. Even if combined, *Johnston* and *Bacehowski* fail to disclose or suggest a flexible container containing an albumin concentration of 20% as required by Claim 1. *Johnston* and *Bacehowski* also fail to disclose or suggest that the container has a seal area free of the albumin concentration and a heat seal formed on the seal area to create a fluid-tight chamber for the albumin concentration as required by Claim 1. In fact, *Bacehowski* fails to even disclose or suggest the term “albumin” or any container holding albumin. Because *Bacehowski* lacks any disclosure of albumin whatsoever, *Bacehowski* cannot disclose or remotely suggest 1) an albumin-filled flexible container 2) with a seal area free of the albumin concentration in accordance with the present claims.

In sum, Appellants respectfully submit that the patentability of Claim 1 over *Johnston* and *Bacehowski* as discussed above also demonstrates that the obviousness rejection of Claims 8 and 26, which depend from Claim 1, is improper. In this regard, even with *Bacehowski* as a reference, the cited art fails to teach or suggest the elements of Claims 8 and 26 in combination with the novel elements of Claim 1.

3. *Johnston and Bell* remain deficient with respect to Claims 9-10 that depend from Claim 1

As discussed above, *Johnston* fails to disclose or suggest every element of independent Claim 1. *Bell* fails to remedy the deficiencies of *Johnston*. Even if combined, *Johnston* and *Bell* fail to disclose or suggest a flexible container containing an albumin concentration of 20% as required by Claim 1. *Johnston* and *Bell* also fail to disclose or suggest that the container has a seal area free of the albumin concentration and a heat seal formed on the seal area to create a fluid-tight chamber for the albumin concentration as required by Claim 1. Moreover, *Bell* not only fails to disclose or suggest albumin anywhere in his disclosure, *Bell* teaches away from the flexible container having permanent peripheral seals as recited in the present claims. For

example, *Bell* discloses a flexible bag made with peripheral peel seals, which teaches away from a container having permanent seals in accordance with the present claims. See, *Bell*, column 5, line 60 to column 6, line 16 and Figure 1.

In sum, Appellants respectfully submit that the patentability of Claim 1 over *Johnston* and *Bell* as discussed above also demonstrates that the obviousness rejection of Claims 9-10, which depend from Claim 1, is improper. In this regard, even with *Bell* as a reference, the cited art fails to teach or suggest the elements of Claims 9-10 in combination with the novel elements of Claim 1.

III. CONCLUSION

For the foregoing reasons, Appellants respectfully submit that the Examiner's Answer does not remedy the deficiencies noted in Appellants' Appeal Brief with respect to the Final Office Action. Therefore, Appellants respectfully request that the Board of Appeals reverse the obviousness rejections with respect to Claims 1-12, 22, 25-26 and 28-33.

No fee is due in connection with this Reply Brief. The Director is authorized to charge any fees that may be required, or to credit any overpayment to Deposit Account No. 02-1818. If such a withdrawal is made, please indicate the Attorney Docket No. 112713-1354 on the account statement.

Respectfully submitted,

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